

## REMARKS / ARGUMENTS

This Amendment is submitted in response to the office action dated February 21, 2003, in connection with the above-identified application. A Notice of Appeal was filed on June 23, 2003. Thus, this paper is timely submitted.

### A. Rejections Under 35 U.S.C. 112, Second Paragraph

The Examiner has rejected Claims 1-11 under 35 U.S.C. 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner states that the use of the word "either" in claim 1 lines 6 and 10 is confusing because it gives two meanings to the claimed limitation. The Examiner also questions what happens to the active substance in step (a)(2). Applicant respectfully disagrees with the Examiner. As stated by the Court of Appeals for the Federal Circuit (the "CAFC") in *Morton International, Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 (Fed. Cir. 1993), "Whether a claim is invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." In the present case, one of ordinary skill in the art would indeed understand the scope of the claim. Step (a) refers to preparing a powder or granulate consisting of (1) *either* the active substance or part thereof and the other ingredients of the solid dosage form, *or* (2) the other ingredients of the dosage form (italics added). One of ordinary skill in the art would understand that to fulfill step (a) one could use at least a fraction of the active substance in combination with the other ingredients or just use the other ingredients by themselves without the active substance. Thus, although alternatives are being provided, the meaning is still understandable by one of ordinary skill in the art. Similarly, in step (b), one of ordinary skill could dispense an auxiliary solvent or alternatively a solution or dispersion that contains the active substance in the auxiliary solvent. When Claim 1 is read in its entirety, it is clear as to what becomes of the active substance in step (a)(2), *i.e.*, the active substance does not become a part of the composition being prepared until step (b)(2).

Moreover, Claims 1-3 are indefinite in the use of the phrase "other pharmaceutical ingredients", "other ingredients" and "all other ingredients." The Examiner states that the phrase is indefinite because it is unclear what "other ingredients" includes. Applicant respectfully disagrees. Applicant respectfully notes that the term other ingredients is used along with the phrase "of the solid dosage form." As stated above, the CAFC has stated that the claim should be read in light of the specification. See, *id.* On page 6, first paragraph, the Specification states, "What the 'other ingredients' of the solid dosage form is concerned [process step (a)], these are not critical and may vary within wide limits. The kind of ingredients used *inter alia* depends on the field where the solid form is intended for, *e.g.* pharmaceuticals, veterinary

products or other areas of application." Since the term "other ingredients" excludes the active substance itself, one of ordinary skill in the art would understand what other ingredients would be appropriate for use in the solid dosage form in combination with the active substance. Pages 11 through 13 set forth non-limiting examples of what the "other ingredients" references. For example, fillers, disintegration agents, lubricants, sweeteners, flavors, taste-masking agents, binders, colorants, buffering agents, acidifying agents and preservatives are all set forth on the same pages. Thus, one of ordinary skill in the art would understand what is claimed by the term "other ingredients."

It is respectfully submitted that this rejection is overcome and should be withdrawn.

#### **B. Rejections Under 35 U.S.C. 102**

Claims 12-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/38679 to Humbert-Droz et al. (hereinafter "*Humbert*"). The Examiner states that *Humbert* teaches fast disintegrating oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant. Applicant respectfully submits that *Humbert* fails to include a disintegration agent.

The CAFC has repeatedly stated that "it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 2131 USPQ 81 (Fed. Cir. 1986). In the present case, this axiom is not met.

Applicant submits that binding agents and disintegration agents are not the same compounds and are not interchangeable agents. The purpose for which these ingredients are included differentiates these agents. A binder is an agent that holds the ingredients together as a solid dosage form (e.g., a tablet). In contrast, a disintegration agent helps in the rapid disintegration of the tablet when the tablet is administered. The Examiner writes that the disintegration agents of the present invention are substantially the same as the binding agents disclosed in *Humbert*. The Examiner states parenthetically that disintegration agents, for example, include agents based on sodium carboxymethyl cellulose and starch, poly-N-vinyl-2-pyrrolidone. However, Applicant urges a more careful reading of the chemical nature of these compounds.

The Specification of the present invention states the following on page 11:

The disintegration agent can be any of those known in the art, e.g., croscarmellose Na; sodium glycolates of starch, e.g., Explotab® and Primojel®; cross-linked poly-N-vinyl-2-pyrrolidones, e.g., Polyplasdone® XL and Kollidon® CL; polymethylmethacrylates, e.g., Eudispert® HV; polysaccharides, e.g., Emcosoy®; or synthetic resins, e.g., Amberlite® IRP88. Preferred disintegration agents are croscarmellose Na, sodium starch glycolate (e.g., Primojel®) and cross-linked poly-N-vinyl-2-pyrrolidones (especially Polyplasdone® XL). The disintegration agent is typically present in an amount of at least 1, preferably of at least 5, and especially of at least 10 weight-% of the total dosage form, e.g. of from 1 up to 20 weight-%, especially of from 1 up to 15 weight%.

In contrast, the specification of *Humbert* on page 3 states the following:

The binding agent (or binder) is primarily used to give sufficient consistency to the formulation to avoid breaking of the article when removed from the blisters and during handling. Binding agents that can be used include polyethylene glycols, acacia, tragacanth, starch, cellulose materials, polyvinylpyrrolidones, alginic acid or a salt or an ester thereof, carrageenan gum, xanthan gum, gellan gum and the like. Also gelatin comes into consideration as a binder.

Applicant would like to note that the ingredients used for a disintegration agent as stated in amended claim 12 do not overlap with the ingredients used for a binding agent. The disintegration agents listed in amended claim 12 are as follows: croscarmellose Na; agents based on sodium carboxymethyl cellulose, poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, polysaccharides or synthetic resins. Moreover, for example, it's cross-linked poly-N-vinyl-2-pyrrolidone used as a disintegration agent not polyvinylpyrrolidones in general.

In view of the fact that the *Humbert* fails to teach each and every element of the claimed invention, it is respectfully submitted that Claim 12 and its dependent claims are in condition for allowance. Applicant respectfully requests that this rejection be withdrawn.

### **C. Rejections under 35 U.S.C. 103**

Claims 1-27 are rejected under 35 U.S.C. 103 as being unpatentable over *Humbert*.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claimed limitations. See, *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

With respect to the method claims, the Examiner stated that *Humbert* is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate, but the extra step does not impart patentability over the prior art. The Examiner states there is no criticality seen in this particular step. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness because *Humbert* is indeed silent regarding the compacting of a suitable amount of the prepared powder or granulate. Furthermore, as illustrated at page 2 of the present specification, the present process for producing a solid dosage form has many advantages over prior art processes. For example, since the active ingredient and its excipients are not dissolved or suspended in a solvent prior to placing them in a mold, the present process assures a uniform content of ingredients, a uniform dosage weight, a less drying time, and the like. Applicant submits that mere conclusory statement that the extra step is not critical is not a sufficient basis for a rejection under 35 U.S.C. 103 when the Specification clearly indicates that the extra step provides significant advantages over prior art processes. Applicant submits that if there is any evidence to the contrary, the burden is on the Patent Office to present the evidence.

With respect to the composition claims, the Examiner states that one of ordinary skill in the art would have been motivated to modify *Humbert*'s composition to obtain the claimed invention because *Humbert* teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within fifteen seconds. As stated earlier, the compositions disclosed in *Humbert* can be differentiated from the compositions of the present invention because *Humbert* does not teach or suggest the use of a disintegration agent. If *Humbert* already taught rapidly dissolving oral dosage forms, then there is certainly not motivation or suggestion to add a disintegration agent to the formulation in *Humbert*. Therefore, Applicant asserts that *Humbert* actually teaches away from the composition claims of the present invention.

In view of the fact that the Examiner has failed to establish a *prima facie* case of obviousness, it is respectfully submitted that this rejection is overcome and should be withdrawn.

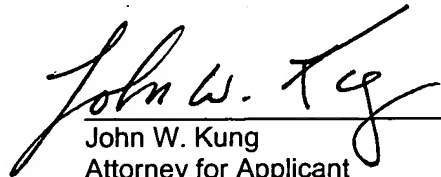
#### **D. Obviousness Type Double Patenting Rejection**

Claims 12-26 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 (the "'531 Patent"). For clarification purposes, Applicant notes that *Humbert* is the PCT priority document of the '531 Patent.

As discussed before, the composition claims of the present invention are significantly different and have at least one additional limitation over claims 1-15 of the '531 Patent. Specifically, the composition claims require the inclusion of a disintegration agent. The '531 Patent does not require the presence of a disintegration agent. According to the Examiner, *Humbert* teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within fifteen seconds. If this were the case, then it would be non-obvious to include a disintegration agent since the compositions disclosed in *Humbert* were already rapidly dissolving.

Thus, it is respectfully submitted that this rejection be withdrawn.

Respectfully submitted,

  
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